

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF PUERTO RICO**

**PHILIPS MEDICAL SYSTEMS PUERTO
RICO, INC.; PHILIPS MEDICAL
SYSTEMS NEDERLAND B.V.; AND
PHILIPS INDIA LIMITED**

Plaintiff-Counterclaim Defendants

v.

**ALPHA BIOMEDICAL AND
DIAGNOSTIC CORP., COOPERATIVA DE
SEGUROS MÚLTIPLES DE PUERTO
RICO**

Defendant-Counterclaimant

Civil Action No. 3:19-cv-01488-BJM

RE: PERMANENT INJUNCTIVE RELIEF
PURSUANT TO THE COMPUTER
FRAUD AND ABUSE ACT, 18 U.S.C.
§1030, PUERTO RICO'S INDUSTRIAL
AND TRADE SECRET PROTECTION
ACT, 10 P.R. LAWS ANN. §§4131-4141;
UNFAIR COMPETITION; DIGITAL
MILLENNIUM COPYRIGHT ACT, 17
U.S.C. §1201; COPYRIGHT
INFRINGEMENT, 17 U.S.C. §101, *et seq.*
AND DEMAND FOR JURY TRIAL

**MOTION REQUESTING INJUNCTIVE RELIEF UNDER RULE 65 (a) OF THE
FEDERAL RULES OF CIVIL PROCEDURE**

TO THE HONORABLE COURT:

COMES NOW Defendant-counterclaimant, Alpha Biomedical and Diagnostic Corp. ("Alpha" or "Defendant"), through the undersigned counsel, and respectfully alleges and prays as follows:

I. NATURE OF THE PETITION

This motion seeks injunctive relief, pursuant to Fed. R. Civ. P. 65(a), against Philips Medical Systems Puerto Rico, Inc. ("Philips PR"), Philips Medical Systems Nederland B.V. ("Philips Nederland") and Philips India Limited ("Philips India") (collectively, "Philips" or "Plaintiffs"). Alpha requests the issuance of a preliminary and permanent injunction to stop Philips from tortiously interfering with Alpha's engagements to its clients and to stop Philips from continuously defaming Alpha. Moreover, a preliminary injunction is required to allow Alpha to

have access to its client's equipment without being encumbered by Philips' improper "mandatory security updates" and for the reestablishment of pre-December 2019 Level 0 access.

Philips' tortious conduct and defamatory actions will continue unless preliminarily and permanently enjoined by this Honorable Court. In the above-referenced action, Alpha has filed counterclaims against Philips (**Dkt. 80**) due to their tortious interference with Alpha's contracts with third parties, and their defamatory statements contained in the Amended Complaint (**Dkt. 9**), which have unjustly harmed, and will continue to harm, Alpha's business and reputation. Philips' actions in bad faith have interfered with Alpha's engagement with its clients and have blocked Alpha's authorized access of Level 0 to the MRI's computers by falsely alleging that the systems require a "mandatory security update". **Dkt. 80, ¶32**. The access now restricted, initially allowed Alpha to offer its diagnostic and maintenance services and generate revenues for the services provided. These improper actions have deprived Alpha of its right to use Level 0. **Dkt. 80, ¶34**. As a result, Alpha stands to lose millions of dollars in service contracts, affecting Alpha's ability to continue its operations and risks losing its business reputation. **Dkt. 80, ¶48**.

Only the immediate intervention of this Honorable Court through preliminary injunction can stop Philips from interfering in the contractual relationships of Alpha and can stop it from denying access to Level 0. Also, this Court's immediate intervention is necessary to enjoin Philips from intimidating Alpha's clients into abandoning their relationships with Alpha and to prevent Philips from continuously defaming Alpha directly to Alpha's clients.

II. THE PRELIMINARY INJUNCTION STANDARD

Rule 65(a) of the Federal Rules of Civil Procedure governs whether a preliminary injunction is warranted. *See* Fed. R. Civ. P. 65 (a). In determining when a party is entitled to a preliminary injunction, the Courts have weight four (4) factors: (1) the moving party's likelihood

of success on the merits; (2) the potential for irreparable harm in the absence of an injunction; (3) whether issuing the injunction will burden the opposing party less than denying an injunction would burden the plaintiffs and (4) the effect, if any, on the public interest. *Sindicato Puertorriqueño de Trabajadores v. Fortuño*, 699 F. 3d. 1 (1st Cir. 2012). “While no single factor is dispositive, the First Circuit Court of Appeals has indicated that the first factor is the *sine qua non* of the preliminary injunction test.” *Torres Rivera v. García Padilla*, 2014 WL 357172, at p. 2 (D.P.R. 2014). As discussed below, Alpha meets all the criteria required for the entry of a permanent and preliminary injunction in its favor.

1. Alpha’s Likelihood of Success on the Merits

a. Philips has tortiously interfered with Alpha’s contractual obligations.

Under Puerto Rico law, an action for tortious interference against third parties that interfere with a valid contract is allowed. *See* Art. 1802 of the Puerto Rico Civil Code, 31 L.P.R.A. §5141. The interfering party and the contracting party who knowingly breaches the contract are jointly liable to the aggrieved party. *Gen. Office Prods. v. A.M. Capen's Sons*, 15 P.R. Offic. Trans. 727 (1984). For a third party to be liable to the aggrieved party, no breach is required. All that is required is that the third party acted tortuously with the knowledge that damage will be caused by a breach. *Id.*, at p. 734. The Puerto Rico Supreme Court has outlined the following elements for a tortious interference claim: (1) there is a contract with which a third party interferes; (2) the third party acted tortuously; (3) there is damage to the plaintiff, and (4) said damage results from the tortious act of the third person. *Id.*

Here, Alpha provides maintenance services to local entities. Many of Alpha’s clients possess Philips brand equipment and their corresponding systems and Alpha had performed its maintenance services for many years without a problem. However, more recently Philips abruptly

ended Alpha's exclusive distribution agreement and it has undertaken affirmative steps to undermine Alpha's operations in Puerto Rico, including but not limited to interfering with Alpha's relationships with its clients.

Philips tortious interference consists of its unilateral elimination of Level 0 access in Alpha clients' equipment under threats by Philips' representatives. Dkt. **80**, ¶81. The FDA regulations require that Philips deliver to Alpha (a third-party service provider) the required tools to provide assembly, installation, adjustment, and testing services to its clients. Therefore, this access was validly granted by these regulations. 21 C.F.R. §820.170; 21 C.F.R. § 801.5; *Medical Devices; Current Good Manufacturing Practice (CGMP) Final Rule; Quality System Regulation*, 1996 WL 33687116, p.p. 81–82. Moreover, Philips' illegal remote access to the equipment installed in Alpha's client's facilities, even when there is no Philips agreement in place, and Philips' delivery of supposed "litigation hold letters" to Alpha's clients with the express intention of intimidating these into abandoning their relationships with Alpha are proof of Philips' interference with Alpha's engagements. Dkt. **80**, ¶81. These malicious acts have interfered with Alpha's ability to provide services to its customers according to terms established in its servicing agreements. Dkt. **80**, ¶82. These actions have caused harm to Alpha by affecting its business, contractual obligations, and revenues. Philips has arbitrarily, irrationally, and intentionally denied access to Alpha with the clear purpose of interfering with the contractual obligations between Alpha and third parties and there is no valid business justification for Philips' conduct by blocking Alpha's access.

Given that Philips' improperly interfered with the servicing agreements between Alpha and its customers, Philips' is liable to Alpha for all damages it has suffered on account of its tortious interference. These damages are currently estimated at \$7,500,000.00. Philips is also liable for the harm suffered by Alpha due to its inability to comply with its contractual obligations, due to its

actions blocking Alpha's access to Philips MRI and unilateral block of Level 0. However, there is no monetary relief that could fully make Alpha whole, for the reasons explained further below.

b. Philips has damaged Alpha's well-established reputation and character.

A party who seeks redress for defamation must prove the following: (1) that information that is false and defamatory was (2) negligently published, with the result that (3) the defamed person suffered real damages. *Segarra Jiménez v. Banco Popular, Inc.* 421 F. Supp. 2d. 452 (2006) at p. 458. "The information published must be injurious," which requires that the libelous publication tend to subject the person to public hatred or contempt, or to deprive it of the benefits of public confidence and social intercourse, or to injure in its business, or in any other way to throw discredit, contempt of dishonor. *Id.* at p. 458.

Here, Philips is attempting to intimidate Alpha's clients into abandoning their relationships with Alpha by sending them letters with copies of the Amended Complaint (**Dkt. 9**). By embarking in this libelous campaign accusing Alpha of dishonest acts that Plaintiffs know are false it is directly and inevitably harming Alpha's well settle reputation and business character. Moreover, Philips sent "litigation hold letters" where it knowingly published false and defamatory information about Alpha, including false statements about Alpha's employees, stating that Alpha has been performing servicing on Philips' Systems of a type that it was not authorized, and stating that Alpha used a fake UserID and IST account, to service some of its clients. The defamatory statements contained in the Amended Complaint, that accompany these "litigation hold letters", include but are not limited to the following:

- a. Stating that after Mr. Bracero's employment with Philips, he transferred or otherwise disposed of without permission his Philips' deactivated login credentials, UserID 34914, and a circumvented copy of the *MRI Response Generator Tool* to

Alpha to allow Alpha and its employees to interconnect and communicate without authorization with plaintiffs' MRI host computers' access-restricted areas, unlock *Philips' CSIP* access protection tools to ultimately gain access to Philip's copyrighted and trade secret property. **Dkt. 9, ¶49; Dkt. 80, ¶108.**

- b. Stating that Alpha and its employees have used Mr. Bracero's deactivated login credentials to bypass and circumvent Philips' software security measures for purposes of accessing data, diagnostic tools, maintenance logs, and other information and software functionalities beyond authorized levels of access. **Dkt. 9, ¶52; Dkt. 80, ¶108.**
- c. Stating that Alpha has been performing servicing on Philips' Systems of a type that it was not authorized or granted a license to do, and of a type that intruded upon Philips' proprietary software and trade secrets. **Dkt. 9, ¶56; Dkt. 80, ¶108.**
- d. Stating that Alpha used Mr. Bracero's Philips' deactivated credentials, UserID 34914 to unlock the Servicios Radiológicos del Este, Condado X-Ray & Ultrasound's (hereinafter, "Condado X-Ray") MRI's host computer's access-restricted areas to access its Philips CSIP Level 1 and Level 2 and the copyrighted and trade secret information contained therein. Plaintiffs further state that the names "victor" and "silva", referring to current Alpha employees, appeared in the corresponding recorded entry. **Dkt. 9, ¶60-65; Dkt. 9-2; Dkt. 80, ¶108.**
- e. Stating that Alpha, through its employees, hacked and/or illegally accessed the *Achieva 1.5T Software* manipulating and/or circumventing access-control measures that effectively control access to *Philips CSIP* by using a fake UserID and IST account, "UserID 12345". **Dkt. 9, ¶74; Dkt. 80, ¶108.**

- f. Stating that Alpha used this alleged fake UserID and IST account, “UserID 12345”, to service Hospital Dr. Susoni and Pavia Breast & Imaging. **Dkt. 9, ¶79-80; Dkt. 80, ¶108.**

All these allegations are false, and Philips is aware of their falsehood. **Dkt. 80, ¶68-72.** Due to Philips’ defamation and tortious interference, Alpha has already lost its fixed-period agreements with the Metro Pavia system. Accordingly, due to all these written communications Alpha has suffered damages and stands to suffer further damages to its business, contractual agreements, and reputation that can only be redressed if permanent and preliminary injunctive relief is granted.

c. Philips’ blocking of Level 0 access violates the FDA’s requirements.

The Federal Food, Drug, and Cosmetic Act (the “Act”), 21 U.S.C. § 301 *et seq.*, regulates, among other things, the manufacturing process of medical devices. 21 U.S.C. § 351(h).

As part of the U.S. Food and Drug Administration’s (“FDA”) mission to prevent the distribution of poorly manufactured drugs and devices, Congress amended the Act in 1976 to include “good manufacturing practices” (GMP), to “improve the quality and reliability of devices and to ensure their integrity from the beginning of manufacture through delivery to the ultimate consumer.” *United States v. 789 Cases, More or Less, of Latex Surgeons' Gloves, an Article of Device*, 799 F. Supp. 1275, 1285, (D.P.R. 1992)

“The GMP regulations for medical devices, 21 C.F.R. § 820, which were promulgated under 21 U.S.C. § 360j(f)(1) and FDA's general rulemaking authority, 21 U.S.C. § 371(a), are binding and have the force and effect of law.” *Id.*, at p. 1287 citing *National Ass'n of Pharmaceutical Manufacturers v. FDA*, 637 F.2d 877, 879–881, 889 (2d Cir.1981).

One of the GMP regulations with force and effect of law is section 820.170, which provides as follows:

(a) Each manufacturer of a device requiring installation shall establish and maintain **adequate installation and inspection instructions, and where appropriate test procedures**. Instructions and procedures shall include directions for ensuring proper installation so that the device will perform as intended after installation. The manufacturer shall distribute the instructions and procedures with the device or otherwise make them available to the person(s) installing the device.

(b) The person installing the device shall ensure that the installation, inspection, and any required testing are performed in accordance with the manufacturer's instructions and procedures and shall document the inspection and any test results to demonstrate proper installation. 21 C.F.R. §820.170.

This provision specifically requires manufacturers of medical devices to provide adequate directions to those that will install and test the device to comply with the purposes of the Act. For its part, “[a]dequate directions for use means directions under which the layman can use a device safely and for the purposes for which it is intended.” 21 C.F.R. § 801.5.

Per the FDA’s updated Final Rule: Quality System Regulation, which details the applicable revisions that led to the current language of Section 820.170, states in its relevant part:

Section 820.170(b) **requires that the person(s) installing the device** follow the instructions and procedures described in Sec. 820.170(a) and **document the activities described in the procedures and instructions to demonstrate proper installation**.

The revised provisions in Sec. 820.170(b) explicitly require that the installation be performed according to the manufacturer's instructions, regardless of whether the installer is employed by or otherwise affiliated with the manufacturer. **Section 820.170(b) requires records to be kept by whomever performs the installation to establish that the installation was performed according to the procedures.** Such records will be available for FDA inspection. FDA does not expect the manufacturer of the finished device to maintain records of installation performed by those installers not affiliated with the manufacturer **but does expect the third-party installer or the user of the device to maintain such records.** (Emphasis added).

Medical Devices; Current Good Manufacturing Practice (CGMP) Final Rule; Quality System Regulation, 1996 WL 33687116, p.p. 81–82.

Philips' decision to block Alpha's access to the service menus is contrary to the FDA's regulations insofar as it hampers Alpha's ability to adequately install, diagnose, and service its clients' equipment. It further affects Alpha's ability to continue operations and risks losing business reputation.

d. Plaintiffs' actions are also actively endangering patients' lives.

Even more importantly, Plaintiffs' actions have endangered Alpha's clients' ability to treat patients in a timely fashion. Plaintiffs' decision to block Level 0 access has unreasonably delayed the availability of one of Alpha's client's MRIs during 24 hours. The nature of the harm the patients could face cannot be accurately quantified. Even a slight interruption of MRIs' operations (let alone one of 24 hours) will cause these patients' irreparable harm. See *Massachusetts Ass'n of Older Americans v. Sharp*, 700 F.2d 749, 753–54 (1st Cir. 1983) (vacating a district court ruling denying preliminary injunctive relief because plaintiff had demonstrated that the terminated Medicaid benefits would have cause patients undue harm, being unable to obtain necessary medical treatment); *Harris v. Bd. of Supervisors, Los Angeles Cty.*, 366 F.3d 754, 766 (9th Cir. 2004) (plaintiffs would have suffered irreparable harm if certain cuts to health facilities were performed and plaintiffs were to face pain, infections, amputations, medical complications and death due to delayed treatment); *Pac. Radiation Oncology, LLC v. Queen's Med. Ctr.*, No. CIV. 12-00064 LEK, 2012 WL 381209, at p. 6 (D. Haw. 2012) (plaintiffs' patients suffering cancer were likely to suffer irreparable harm if preliminary injunction was denied or delayed); *Nat'l Ass'n of Psychiatric Treatment Centers v. Weinberger*, 661 F. Supp. 76, 81 (D. Colo. 1986) (preliminary injunction was justified to enjoin the implementation of new terms of reimbursement for care

expenses when the interruption of said care would have been deleterious to the patients and their families).

Here, Alpha also seeks the reestablishment of pre-December 2019 Level 0 access. This would ensure that Alpha's client's patients have assured access to the relevant equipment that might save their lives.

The facts stated above, in conjunction with the applicable law, convincingly shows that Alpha will likely succeed on the merits. Thus, the first prong required under Fed. R. Civ. P. 65 (a) weighs in favor of issuing the permanent and preliminary injunction sought by Alpha.

B. Alpha is exposed to irreparable harm

For purposes of a preliminary injunction, an injury will only be considered irreparable if no adequate remedy for the injury exists at law. *See Total Petroleum v. Colón Colón*, 577 F. Supp. 2d. 537, 551 (D.P.R. 2008). The threat of substantial loss of business and certainly bankruptcy qualified as the sort of irreparable harm needed to support a preliminary injunction. *Doran v. Salem Inn, Inc.*, 422 U.S. 922, 932 (1975). Moreover, a substantial loss to a business is sufficient to prove irreparable harm. *Rio Grande Cmty. Health Ctr., Inc. v. Rullan*, 397 F.3d 56, 76 (1st Cir. 2005); *Semmes Motors, Inc. v. Ford Motor Co.*, 429 F.2d 1197 (2d Cir.1970).

Through its actions, Philips' has undermined Alpha's operations in Puerto Rico causing irreparable harm to the business's ability to **generate revenues, to its reputation, and the alienation of customers**. Moreover, it has limited Alpha's ability to expand its services to new customers. These actions have threatened Alpha's business, which as a result, has caused losses to the business. This has irreparably harm Alpha's business character and ability to expand its business within Puerto Rico.

Here, Philips has knowingly published defamatory information about Alpha to Alpha's clients to intimidate Alpha's clients into abandoning their relationships with Alpha and has blocked Alpha's authorized access of Level 0 to the MRI's computers by falsely alleging that the system requires a "mandatory security update". Due to these unlawful actions, Alpha lost fixed-period agreements with third parties, it is exposed to lose many more services agreements and, as a competitive business, it is suffering irreparable harm due to its unavailability to comply with its contractual obligations and business operations. Moreover, all these affect Alpha's well-settled reputation and business character, which results in direct irreparable harm to the business. If Philips is not enjoined by this Honorable Court, Alpha's business will continue to suffer direct harm because of Philips interference with its contractual obligations, Philips false statements about Alpha, and Philips actions blocking Alpha's access to Level 0. In conclusion, these actions are irreparably harming Alpha's business, reputation, and ability to save hundreds of lives. Therefore, the requested injunction relief is the only adequate remedy available to Alpha and if not granted, Alpha is bound to suffer additional irreparable injuries.

Additionally, as discussed in the preceding section, unless enjoined, Philips' actions will continue to cause irreparable harm to Alpha's clients' patients.

C. The Balance of Equities Favors the Injunction

The requirement to "balance the equities" forces the Court to look at the "balance of relevant impositions", that is, whether the hardship to Phillips if it is wrongfully enjoined will outweigh the harm to the Alpha if it is denied an injunction it deserves. See *Ross-Simons Warwick, Inc. v. Baccarat, Inc.*, 102 F. 3^d 12, 15 (1st Cir. 1996). That balance favors Alpha's position.

Here, the damage caused to Alpha by Philip's improper actions, as detailed in the preceding sections, clearly outweighs any harm that Philips may suffer. It is clear that if the injunction is

issued, it will not affect Philip's operation and business in any way since it will only be stopped from executing wrongful actions and will be forced to grant access to Alpha to complete what it is legally authorized to do. After all, that is how Philips was supposed to act in the first place. Moreover, the injunction will ensure that Alpha's clients' patients receive adequate treatment.

The balance of equities directs the issuance of the injunction in favor of Alpha since the injunction is the only way to protect Alpha's business and reputation. d

D. Impact on the Public Interest involved

The public interest also weighs in favor of granting the injunction. This factor refers to "the public interest in the issuance of the injunction itself." *Braintree Labs, Inc. v. Citigroup Glob Markets, Inc.* 622 F. 3d. 36, 45 n.8 (1st Cir. 2010). In this case, issuing an injunction would stop Philips from haring Alpha's reputation. Moreover, it would allow Alpha to continue performing under the terms of the services agreements without further tortious interference from Philips.

In the above-referenced case, the public interest lies in protecting the life of third parties benefiting from the services provided by Alpha; therefore, the issuance of preliminary and permanent injunctions is likely to also avoid unnecessary loss of life. No public interest can be served by allowing Philips to continue denying access to Alpha and to allowing it to sabotage Alpha's reputation and servicing agreements, advancing its interest at the expense of Alpha's business.

V. CONCLUSION

As evidenced by the foregoing discussion, all the factors that the Court must consider weight in Alpha's favor.

Alpha has demonstrated a high likelihood of success in those claims; that it has suffered and will continue to suffer irreparable injuries to its public reputation and its business if this request

Motion Requesting Injunctive Relief

Page 13

for a permanent and preliminary injunction is not granted; and that the public interest and the equities favor the issuance of a preliminary injunction in favor of Alpha.

WHEREFORE, Alpha respectfully requests this Honorable Court to grant a preliminary and permanent injunction ordering Philips to a) stop tortiously interfering with Alpha's engagements to its clients; b) to stop continuously defaming Alpha; c) refrain from knowingly publishing false and defamatory information about Alpha in prejudice of its reputation and character; d) allowing Alpha to have access to its client's equipment without being encumbered by Philips' "mandatory security updates" and for the reestablishment of pre-December 2019 Level 0 access.

RESPECTFULLY SUBMITTED.

In San Juan, Puerto Rico, this 30th day of December 2020.

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